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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 03-183

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]
on 07/25/2008
Signature
Typed or printed name Keum J. Park

Application Number	Filed
10/801,307	03/16/2004

First Named Inventor: Todd Robida

Art Unit	Examiner
3752	Jason J. Boeckmann

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 42,059
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34

Signature
Keum J. Park
Typed or printed name
908-518-7700
Telephone number
07/25/2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _ forms are submitted.

Reasons for requesting pre-appellate review:

1) The Examiner's Objection to the Drawings is Erroneous

In the Office Action, the Examiner objects to the drawings as failing to show every feature of the invention specified in the claims. Specifically, the Examiner requests Applicant to show "two valve seats, the first position, the second position, and the default neutral position of the valve" in the drawings or to cancel the features from the claims.

The Examiner's objection is erroneous. The amended drawings are in compliance with 37 C.F.R. 1.83(a). The Examiner erroneously states that "a schematic drawing cannot represent the open and closed positions of the valve when only details of relative positions of the internal parts and features of the valve can clearly show the respective positions." Applicant respectfully disagrees. 37 C.F.R. 1.83(a) clearly states that features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, ***should*** be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box). In this regard, it is respectfully submitted that one of ordinary skill in the art would readily understand the three possible positions of the valve that is described and claimed herein, for example, by following the instructions in the specification regarding the construction of such a valve. The valve according to one embodiment, is exemplified, for example, in Figure 9 and the valve in the first position, second position, and default position are illustrated, for example, in FIGS. 17A, 17B, and 17C, respectively, in the form of a labeled representation in accordance with 37 C.F.R. 1.83(a). One of skill in the art would readily understand that the valve 1) can be pneumatically operated to open the first valve seat while closing the second valve seat, 2) can be pneumatically operated to close the first valve seat while opening the second valve seat, or 3) can occupy a central position where the first and second valve seats are open (the default neutral position) when supply pressure operating the valve is removed. Further details are provided in the discussion to follow regarding 35 U.S.C. § 112, first paragraph.

2) The Examiner's Rejection Under 35 U.S.C. §112, first paragraph is Erroneous

In the Office Action, the Examiner maintained his rejection of claims 2, 4, 11 and 19 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Specifically, the Examiner states that the "Examiner is unsure as to how the valve returns to its

neutral state without the use of a spring return mechanism. If the valve is in a closed position, and the pneumatic forces are removed from both pneumatic ports simultaneously, how does the valve member move from the closed position to the open position without the use of a spring return mechanism?" This enablement rejection is erroneous and the Examiner has applied an improper legal standard.

Applicant states that Examiner's enablement rejection is legally improper and furthermore, is based on his lack of fundamental understanding of the mechanical nature of Applicant's device and is not based on a lack of teaching within the disclosure of how to make and to use the invention of the claims. Applicant has repeatedly pointed out to the Examiner all of the teachings in the specification that support the double pneumatic acting valve of the present invention. The fact that the Examiner, himself, lacks clarity about the valve mechanism of the present invention is not a proper legal basis for an enablement rejection.

The following is a well-established PTO procedure, based on the statute and legal precedent:

> A specification disclosure which contains a teaching of the near and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented ***must*** be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is ***reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support.***

MPEP 2164.04 (emphasis added)(citing *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (CCPA 1971).

The Examiner has put forth no ***reason to doubt*** that the detailed teachings and instructions in the specification will yield a valve having a default neutral state in which all valve seats of the three-way valve remain open when a supply pressure operating the valve is removed. In the absence of evidence or prior art, the Examiner has not satisfied the burden of providing such reason to doubt the object truth of the statements in Applicant's specification.

Rather than providing any proof, the Examiner poses questions. For example, in the Final Office Action, the Examiner poses:

> If the valve has one valve seat "open" and one valve seat "closed," an the supply pressure is removed form [sic] that "closed" valve seat, what is forcing the [sic] that particular valve seat to automatically go back to the "open" position? Is it not going to go back to the "open" position all by itself. It needs some sort of force acting on it to move it form [sic] the "closed" position back to the "open" position. If the valve seat moves back to its "open" position by a force of a

> pneumatic return, then how does the valve go to the default neutral state when the supply pressure is removed?
> (page 5, first full paragraph, Final Office Action)

Applicant states that the above indicates that the Examiner appears to take the position that although there the disclosure teaches ***how to make*** the three-way valve of the present invention, the specification somehow fails to show ***how the valve works***. However, "it is ***not*** a requirement of patentability that an inventor correctly set forth, or even know, ***how or why the invention works***." *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989)(emphasis added); *see also Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983)("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.") Even though it is not required, the specification explains how and why the invention works.

In the DETAILED DESCRIPTION of the specification, Applicant provides not only the structure of the new three-way valve of the present invention (Figure 9), but also provides details regarding a simply method of manufacture of such a device, based on an existing three-way valve and provides illustrative drawings of both the prior art and the improved valve of the present invention. *See* paragraphs [0032] to [0033] and [0040] to [0043].

Applicant has previously explained to the Examiner in great detail how the valve returns to its neutral state without the use of a spring return mechanism. Specifically, Applicant has drawn the Examiner's attention to the default structure of Applicant's device in contrast to prior art three-way valves. In the Takasago three-way valve of Figures 2-8, due to the presence of the spring return in the valve (see Figure 5), there is ***always an actuating force on the valve, even when the supply pressure operating the valve is removed, e.g., when the valve is not in use*** (see paragraph [0002] of the Background and see also the October 10, 2006 Amendment and Response in which Applicant describes in great detail the mechanics of the Takasago valve with a spring return). In contrast, in the present invention, "all valve seats of the medical device [are] ***open*** when the unit is not in use." (paragraph [0005]) (emphasis added).

Given that the Examiner rejected the claims as not enabled despite the above disclosure which provides enabling support, it appears that the Examiner questions that the invention has a ***credible utility***. However, the Examiner has the initial burden of challenging a ***presumptively correct assertion of utility*** in the disclosure. Otherwise, the Examiner cannot reject the teachings

in the disclosure unless the Examiner has reason to doubt the objective truth of the statements contained in the written description. *In re Brana*, 51 F.3d 1560, 1564 n.12, 34 USPQ2d 1436, 1439 n.12 (Fed. Cir. 1995), *cited with approval in, In re Cortwright*, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999). Applicants respectfully state that the Examiner has not met this burden.

Applicant reiterates that the claims are fully enabled and requests that the Examiner reconsider and withdraw his rejection.

3) The Examiner's Rejection Under 35 U.S.C. §103(a) – Kintner and acknowledged state of the art is erroneous

Claims 2, 4, 5, 7, 10-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the acknowledged prior art of Figure 1 in view of Kintner (U.S. Patent No. 3,426,799). Claims 1, 3, 6, and 14-20 are rejected as being unpatentable in light of acknowledged prior art of figure 1-8, in view of Kintner.

The Examiner's primary argument appears to be that Figure 1 of Kintner teaches all of the elements of the invention of independent claim 1 except that it fails to teach "that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats." To remedy such deficiency, the Examiner then turns to Kintner, a 1969 patent document for an "Automatic Valve." However, Kintner fails as a primary reference. The valve of Kintner simply does not disclose a dual pneumatic actuated three-way valve comprising two air pressure diaphragms and two valve seats that is dual actuated with no spring return mechanism.

Upon reviewing the valve device of Kintner in detail, it becomes apparent why the device of Kintner fails to teach the claimed invention and why the combination with the acknowledged prior art fails to establish a *prima facie* case of obviousness. Kintner expressly ***teaches away*** from valves such as those of the present invention that include air pressure diaphragms and valve seats, dismissing them as undesirable. Instead of valves having seats and diaphragms, Kintner advocates a valve actuated by a "piston which can be moved by application of extremely small pressures to operate the valve" and which dispenses with the need for "costly stems, and unreliable seats and diaphragms." (col.1, lines 7-15).

Entirely different in its mechanism from the valves of the present invention, the Kintner valve involves a sliding piston assembly that moves from a default closed "seated position" to an "open position." Specifically, Kintner teaches "floating O-rings" wrapped around a series of

pistons that are mounted on piston rods. In its default state, as shown in Fig. 1 of Kintner, the valve is in the "closed position." (col. 1, lines 35-37). Then, "[i]n operation, the O-ring actually "floats" radially outwardly as it moves from the position shown in Fig. 1 to that shown in Fig. 2 since the stretched O-ring leaves its seating position during such movement as it slides across the recessed area 16 in the flow stream. Line pressures immediately encapsulate the O-ring." (col. 2, lines 48-66).

4) The Examiner's Rejection Under 35 U.S.C. §103(a) over Liston and Kintner is erroneous

Claims 1-7 and 10-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Liston (U.S. Pat. No. 3,817,425) in view of Kintner. This rejection is respectfully traversed.

Liston fails to correct the deficiency of Kintner, as discussed above. All presently pending claims require a dual pneumatic actuated three-way valve comprising two valve seats. Kintner, on the other hand, does not teach such a valve but rather, teaches piston-operated valved. It is respectfully requested that the remarks presented in Applicant's response filed October 10, 2006 and March 26, 2007 be herein incorporated by reference.

5) The Examiner's Rejection Under 35 U.S.C. §103(a) over acknowledged prior art, Liston and Chemline Plastics is erroneous

Claims 8-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over acknowledged prior art, in view of Kintner, further in view of Chemline Plastics (2001). This rejection is respectfully traversed. Liston and Chemline Plastics fails to address any of the underlying deficiencies of Kintner, as discussed above.

Independent claim 5, upon which claims 8-9 depend, is patentable for the reasons discussed above and the rejection of claims 8-9 fails for the same fundamental reasons and in addition, these claims provide further distinguishing features.